

REMARKS

Claims 1, 2, 4-17 and 44-47 are pending. No new matter has been added by way of the above amendments. For instance, claim 2 has been amended to incorporate the subject matter of originally filed claim 1. Claim 4 has been amended to recite the hybridization conditions disclosed at page 9 of the specification. Claim 5 has been amended to recite a composition and claim 15 has been amended to be properly dependent. New claim 44 is supported by the present specification at page 13, lines 1-5 and Figure 1. New claim 46 is supported by originally filed claim 1. Lastly, new claims 45 and 47 are supported by the hybridization conditions disclosed at page 9 of the specification. Accordingly, no new matter has been added.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

Objections to the Claims

The Examiner has objected to claims 2-4, 5, 11-12 and 15 for the reasons recited at page 3 of the outstanding Office Action. Applicants traverse these rejections.

First, the Examiner asserts that the claims depend from non-elected claim 1. Applicants have amended the claims to remove this objection.

Second, the Examiner indicates that claim 4 contains a

typographical error. Applicants respectfully submit that no typographical errors are present in currently pending claim 4.

Third, the Examiner indicates that claims 5 and 15 contain subject matter which is non-elected. Applicants traverse and submit that the non-elected subject matter has been removed from these claims.

Accordingly, each of the Examiner's objections are moot. Reconsideration and withdrawal thereof are respectfully requested.

Issues Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claims 2-4, 5, 11, 12 and 15 under 35 U.S.C. § 112, second paragraph, for the reasons recited at pages 3 and 4 of the outstanding Office Action. Applicants respectfully traverse these rejections.

First, the Examiner indicates that the recitation of "capable of participating in the human PTCH/SHH pathway" in claim 1 is unclear. Applicants traverse this rejection and submitted that the claims no longer recite this limitation. Thus, this rejection is moot. Reconsideration and withdrawal thereof are respectfully requested.

Second, the Examiner indicates that the recitation of "capable of specifically hybridizing" in claim 4 is unclear. Applicants traverse and submit that the hybridization conditions are now recited in claim 4. Thus, this rejection is moot. Reconsideration and withdrawal thereof are respectfully requested.

Third, the Examiner indicates that the recitation of "use as a medicament" in claim 5 is unclear. Applicants traverse and submit that claim 5 no longer includes such a phrase. Thus, this rejection is moot. Reconsideration and withdrawal thereof are respectfully requested.

Issues Under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected claim 15 under 35 U.S.C. § 112, first paragraph, for the reasons recited at pages 4 and 5 of the outstanding Office Action. Applicants respectfully traverse this rejection.

The Examiner asserts that claim 15 relates to a kit for the detection of human PTCH2 gene, however, the claims encompass any PTCH2 gene. Applicants traverse and submit that claim 15 requires the presence of a nucleic acid according to any one of claims 2 or 4. These nucleic acids are specifically defined. Thus, this rejection is moot. Reconsideration and withdrawal thereof are respectfully requested.

The Examiner has also rejected claims 2-4, 5, 11, 12 and 15 under 35 U.S.C. § 112, first paragraph, asserting that the specification, while being enabling for a nucleic acid that encodes SEQ ID NO.1 and a nucleic acid that encodes PTCH2, vectors, host cells and kits, does not reasonably provide enablement for any nucleic acid that encodes an "analog or variant" as in SEQ ID NO:1, or any nucleic acid that hybridizes to

a nucleic acid of SEQ ID NO:1. Applicants respectfully traverse this rejection.

First, Applicants point out that claim 2 no longer includes the "analog" or "variant" language. Second, Applicants point out that claim 4 now recites specific hybridization conditions. These hybridization conditions, coupled with the structure recited in claim 2, are fully enabled by the present specification. Thus, the Examiner is respectfully requested to withdraw this rejection.

Issues Under 35 U.S.C. § 102(b)

The Examiner has rejected claims 2-5, 11 and 12 under 35 U.S.C. § 102(b) as being anticipated by Motoyama et al. Applicants respectfully traverse this rejection.

The present invention relates to the sequence of the human patched2 gene, while Motoyama deals with the corresponding mouse sequence. The sequences exhibit 91% homology on the amino acid level. The species-specific importance of the difference is discussed in the present description at page 21, lines 8-10 and 17-19. In this context, the Examiner should note that the differences are present in the carboxyl terminus, and it is known in the art that signaling involves the carboxyl terminus of the patched proteins (see Motoyama). Further, the gene encoding the human patched2 protein was shown for the first time according to the present invention (page 13, lines 20-21) to be located in the chromosomal region 1p33-34, which is a region well known to the

skilled person to often be implicated in cancer. The patentability of claim 2 with respect to Motoyama is also supported by the chromosomal location of the human gene. The finding that patched2 mRNA was unregulated in BCCs, i.e., in tumours with frequent patched1 mutations and in other tumour types implies that claim 2 defines a target gene of the patched/sonic hedgehog signaling pathway as discussed in page 23 in the description.

Motoyama only mentions the role of patched in carcinomas and not patched2. Patched only exhibits 56% homology with patched2 (page 2, third column, Motoyama). In fact, on page 3, lines 10-12, it is clearly stated that "patched2 transcripts were detected only in the invaginating epithelial cells".

In view of the lack of disclosure of the presently claimed sequences, there is no anticipation of the present claims based on Motoyama. Reconsideration and withdrawal of this rejection are respectfully requested.

The Examiner has also rejected claims 2-5, 11 and 13 under 35 U.S.C. § 102(e) as being anticipated by Sauvage et al., USP 6,348,575. Applicants respectfully traverse this rejection.

The sequence disclosed in Sauvage is distinct from the presently claimed subject matter. Similar to the above, Sauvage fails to suggest or disclose the presently claimed sequences. Accordingly, no anticipation exists. Reconsideration and withdrawal of this rejection are respectfully requested.

Lastly, the Examiner has rejected claim 4 under 35 U.S.C. §

102(b) as being anticipated by the Boehringer Mannheim 1991 catalog. Applicants respectfully traverse this rejection. Applicants submit that claim 4 recites specific hybridization conditions. There is no indication that the random primers disclosed in the Boehringer Mannheim 1991 catalog would hybridize to a nucleic acid sequence encoding SEQ ID NO.1. Accordingly, this rejection is moot. Reconsideration and withdrawal thereof are respectfully requested.

Issues Under 35 U.S.C. § 103(a)

The Examiner has rejected claims 2-4, 5, 11, 12 and 15 under 35 U.S.C. § 103(a) as being obvious over Motoyama. Applicants respectfully traverse this rejection. In particular, as indicated above, the sequences disclosed by the present invention compared to Motoyama are distinct. No motivation exists based upon the Motoyama reference to arrive at the currently claimed subject matter. Accordingly, the Examiner has failed to present a valid *prima facie* case of obviousness. Reconsideration and withdrawal of this rejection are respectfully requested.

Lastly, the Examiner has rejected claims 2-5, 11, 12 and 15 under 35 U.S.C. § 103(a) as being obvious over Sauvage. Applicants respectfully traverse this rejection. As indicated above, the presently claimed sequences are distinct from the sequences disclosed in Sauvage. Moreover, no motivation exists in the Sauvage reference to arrive at the presently claimed

sequences. Accordingly, the Examiner has failed to present a valid *prima facie* case of obviousness. Reconsideration and withdrawal of this rejection are respectfully requested.

In view of the above, Applicants respectfully submit that the present claims define subject matter which is patentable over the cited art. Accordingly, the Examiner is respectfully requested to withdraw all rejections and allow the currently pending claims.

If the Examiner has any questions or comments, please contact Craig M. McRobbie, Reg. No. 42,874 at the offices of Birch, Stewart, Kolasch & Birch, LLP at (703) 205-8000 in the Washington, D.C. area.

Pursuant to the provisions of 37 C.F.R. §§ 1.17 and 1.136(a), the Applicants hereby petition for an extension of two (2) months to April 12, 2003 in which to file a reply to the Office Action. The required fee of \$410.00 is enclosed herewith.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees

Application No.: 09/807,007

required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17;
particularly, extension of time fees.

Respectfully submitted,

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Attachment: Version with Markings to Show Changes Made



Application No.: 09/807,007

VERSION WITH MARKING TO SHOW CHANGES MADE

IN THE CLAIMS:

Claims 3 and 18-43 have been cancelled.

The claims have been amended as follows:

2. (Amended) [A] An isolated nucleic acid encoding a human protein, which is essentially comprised of SEQ ID NO: 1 [protein according to claim 1].

4. (Amended) An isolated nucleic acid [capable of specifically hybridising] which hybridizes to [a] the nucleic acid according to claim 2, [or 3] wherein said hybridization occurs at a salt concentration of less than 1.0 M Na ion, at pH 7.0-8.3 and at a temperature of at least about 30°C.

5. (Twice Amended) A composition, comprising the [protein according to claim 1 or a] nucleic acid according to claim 2 [for use as a medicament].

15. (Amended) A kit for the detection of a human PTCH2 gene [or polypeptide] comprising in a container [a molecule selected from the group consisting of] a nucleic acid according to any one of claims 2 or 4 [2-4], a protein according to claim 1 or an

Application No.: 09/807,007

antibody according to claim 13].

Claims 44-47 have been added.